OECD Xenotransplantation Policies and Public Participation

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Erich Griessler

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OECD Xenotransplantation Policies and Public Participation

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April 2012

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Founded in 1963 by two prominent Austrians living in exile – the sociologist Paul F. Lazarsfeld and the economist Oskar Morgenstern – with the financial support from the Ford Foundation, the Austrian Federal Ministry of Education, and the City of Vienna, the Institute for Advanced Studies (IHS) is the first institution for postgraduate education and research in economics and the social sciences in Austria. The **Sociological Series** presents research done at the Department of Sociology and aims to share "work in progress" in a timely way before formal publication. As usual, authors bear full responsibility for the content of their contributions.

Das Institut für Höhere Studien (IHS) wurde im Jahr 1963 von zwei prominenten Exilösterreichern – dem Soziologen Paul F. Lazarsfeld und dem Ökonomen Oskar Morgenstern – mit Hilfe der Ford-Stiftung, des Österreichischen Bundesministeriums für Unterricht und der Stadt Wien gegründet und ist somit die erste nachuniversitäre Lehr- und Forschungsstätte für die Sozial- und Wirtschafts-wissenschaften in Österreich. Die **Reihe Soziologie** bietet Einblick in die Forschungsarbeit der Abteilung für Soziologie und verfolgt das Ziel, abteilungsinterne Diskussionsbeiträge einer breiteren fachinternen Öffentlichkeit zugänglich zu machen. Die inhaltliche Verantwortung für die veröffentlichten Beiträge liegt bei den Autoren und Autorinnen.

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1 Introduction

Citizens, policymakers and social scientists often call for citizen participation for reasons of democratic legitimacy and effectiveness. A field in which this has been vigorously claimed is science and technology policy. Thus, many countries witnessed the introduction of Participatory Technology Assessment (PTA). The "litmus test" of PTA and of citizen participation, however, is their impact on policy making. But can PTA keep its promises and increase the influence of citizens' voices on decision-making? What in actual fact is the impact of PTA on decision-making? How can we increase it?

In order to answer these questions the project "Impact of Citizen Participation on Decision Making in a Knowledge Intensive Policy Field" (CIT-PART) comparatively studies the impact of PTA and technology assessment (TA) on policy making in Austria, Canada, Denmark, Italy, Latvia, The Netherlands, Sweden, Switzerland, United Kingdom, the European Commission, the OECD and the Holy See. Thereof the project draws conclusions about the potential impact of institutionalized citizen participation at EU level.

This project addresses these questions through the reactions of various political systems to the challenge of xenotransplantation, which stands for the transplantation of animal organs, tissues or cells into humans. Xenotransplantation is highly controversial: Its advocates perceive it as promising since it could help to remedy the shortage of human transplants. Its opponents insist that it involves too many risks - most prominently infection from animals to humans - and ethical questions.

By adopting a theoretical approach of “social practices” this project makes the assumption that the impact of citizen participation on decision-making is not only dependent on the quality of the PTA process itself but on practices of policymakers in which PTA is embedded. Following from this theoretical approach, the project applies qualitative methods of empirical research.

1.1 Case selection

Although the OECD, unlike nation states and the EU, for the most part lacks regulatory competence and, unlike the International Monetary Fund and the World Bank, has almost no financial means to advance its policies, it nevertheless plays an important role in international policy as an intergovernmental platform for the exchange and promotion of policy ideas and instruments. As a hybrid between an expert and an intergovernmental organization and as has been mentioned largely devoid of money and laws that as generalized symbolic media could promote its policies, the OECD is forced to apply much softer measures. It is limited to providing expertise and knowledge and, as political scientist Martin Marcussen put it, to playing the “idea game” to reach its objectives (Marcussen 2004).

Jörg Dostal's analysis of OECD labor market policy also provides an illustrative case of how the OECD employs knowledge to promote its policy ideas. He uses the example of the Directorate for Education Employment Labor and Social Affairs (DEELSA) to describe how the OECD frequently acts as an initiator in promoting ideas, thus preparing "the ground for subsequent (…) regulation" at the national and EU level (Dostal 2004: 445).

By playing the idea game, the OECD often enters into emerging policy fields with the objective to create awareness for, as well as coordination and harmonization of, national policies at the international level. The OECD also acted in this way in the case of xenotransplantation. It's Working Party on Biotechnology (WPB), a subcommittee of the Committee for Scientific and Technological Policy (CSTP), addressed xenotransplantation as early as 1995 as an emerging policy issue. This engagement followed its previous activities regarding human health related applications of biotechnology (OECD Observer 1999). The instruments the OECD applied were:

- writing and circulating policy papers (OECD 1996, OECD 1999a, OECD/WHO 2000);
- organizing two conferences: the New York Workshop and a OECD/WHO Consultation in Paris in 1998 and 2000, respectively, which assembled experts and policy-makers from Member and Non-Member States and international organizations;
- setting up a data bank of xenotransplantation policies in its Member States; and
- forging links with Member State governments, the WHO (OECD 1999b) and the Council of Europe on this matter.

As will be described in this paper, the OECD focused on the discussion of recent scientific developments, the assessment of the socio-economic costs and benefits of xenotransplantation and its alternatives as well as the establishment of standards and infrastructures for international xenotransplantation surveillance. To a much lesser extent it discussed the ethical problems posed by xenotransplantation. The OECD terminated its activities in 2001, leaving international policy making deliberately to the WHO, as it already suggested in its first policy paper in 1996 (OECD 1996: 22).

Although the OECD shares little commonalities with nation states, analyzed in other CIT-PART case studies, it is an important case for this research project. An analysis of the OECD provides the chance to examine a crucial aspect of science and technology policy in general and xenotransplantation policies in particular, i.e. its international dynamics. Regulation of xenotransplantation does not only occur at the national level. It is also critically influenced by international discussion at the OECD, the Council of Europe and the WHO.

The OECD created a platform for policymakers from nation states and international organizations as well as experts from public research and private industry to promote exchange and policy learning. In this way, national and international xenotransplantation policies became interconnected.

A second aspect of the international dynamics of xenotransplantation research and regulation relates to the particular difficulties of realizing citizen participation in science and technology policy at the international level. Practicing citizen participation is already a demanding exercise for national governments but how can highly complex international and supranational bureaucracies cope with this challenge? The OECD case provides an opportunity to examine these questions.

1.2 Methods

As Porter and Webb point out, the OECD received little attention in the international relations literature (Porter/Webb 2007: 2). Existing analysis often focuses on the OECD's role in international welfare and labor market policies (Salzman 2000, Noaksson/Jacobsoson 2003, Armingeon/Beyeler 2004, Dostal 2004). An exception to this is Mahon and McBride's edited volume on the OECD, which not only assembles research on different policy fields – including biotechnology (Drouillard/Gold 2008) - but also focuses on the organization's role as actor in global governance (Mahon/McBride 2008). Literature on the OECD's xenotransplantation policies is also very limited. Existing work mainly remains descriptive, summarizing the OECD's positions without analyzing the policy process (Paslack 2008, Hüsing et al. 1998, Hüsing 2004). The case study takes this literature into account.

A second type of material this case study is based on is official OECD documents (OECD 1996, 1999, 2000, OECD/WHO 2001).

A third source were eleven interviews with civil servants and researchers from OECD Member States and the OECD who were previously, and/or currently affiliated to this organization as temporary experts, permanent Secretariat staff or members of Committees, Working Parties and the Council. A criterion for their recruitment was knowledge about the OECD's xenotransplantation policies in particular and more generally about its science and technology policies as well as experience with the OECD as an organization.

Interview partners were recruited by applying a snowball system. In a first round two researchers were interviewed who worked as experts at the OECD for several years and dealt with science and health policies respectively. These interviews, carried out in the summer of 2010, provided first insights into the OECD's makeup as an organization and helped to identify more interview partners. Thereafter, two civil servants of a Member State were interviewed, who acted as liaisons between their national civil service and the OECD. These interviews revealed more information about the interplay between Member States and

the OECD in policy making. They also resulted in additional informants. These interviews were followed by a research trip to the OECD headquarters in Paris in October 2010, which included two interviews with Directorate staff and three interviews with representatives of a Member State. Data collection, in terms of interviews, was finalized in the spring of 2011 with interviews with two Member State delegates, who served as members of the OECD's Working Party on Biotechnology.

With one exception the interviews were carried out face to face. One interview was carried out as a telephone interview for economic reasons. Interviews were based on a guideline shared by all CIT-PART partners which was derived from the methodological guidebook and was adapted according to necessity, primarily the interviewee's position in the OECD and his/her direct involvement with xenotransplantation policies.[1] The interviews lasted between approximately thirty minutes to one hour; almost all of them were taped and fully transcribed. Two interviewees requested that their interviews were not be taped for reasons of confidentiality. In these cases records were produced immediately after the interview. Transcripts and records were analyzed by qualitative methods (thematic analysis). Interviews were used to describe the OECD's xenotransplantation policies and to examine social practices of policy making, technology assessment and citizen participation. In a first round of analysis, themes were identified in each interview. In a second round, these themes were compared across interviews and theories were synthesized. Thematic analysis was supported by Atlas.ti, a software tool specifically developed for qualitative analysis. Interviews are quoted within the text. Roman numbers in brackets refer to the interview, while the numbers refer to the relevant lines within the transcript or record.

1.3 Acknowledgements

First of all I am most grateful to the European Commission for funding this research project. In addition I want to thank all interview partners for their unhesitating and welcoming readiness to participate in the project. Without their friendly and open support this research would have simply been impossible. I also want to thank Claudia Jandrisic for transcription and Alexander Lang for compiling and categorizing a participant list of the New York Workshop and the OECD/WHO Consultation. I particularly want to thank Karina Weitzer for transcription and language editing. Finally I want to acknowledge Peter Biegelbauer for his valuable comments on a draft version of this paper.

1.4 Layout of the paper

The paper starts with a description of the OECD as an organization (chapter 2) and continues with an outline of OECD xenotransplantation policies (chapter 3). It describes its development from the first background paper to an official joint document of the OECD and

[1] See Annex

WHO. Chapter 4 summarizes the role of different actors in this policy process. Chapter 5 analyses important social practices in the area of policy making as well as citizen participation. The concluding section (chapter 6) recapitulates the main findings and addresses the main research questions of the CIT-PART project.

2 The OECD as an Organization

This chapter is dedicated to an analysis of the OECD as an organization. It portrays its mission as being a policy forum, think tank and policy advisor on the topics it deals with. The section continues by highlighting the features of the OECD that characterize it as an intrinsically political organization and concludes with a description of its organizational structure.

2.1 Mission

The OECD was established in 1961. It is the successor institution to the Organization for European Economic Co-operation (OEEC), which was established in postwar Europe to co-ordinate the Marshall Plan, which aimed to achieve economic reconstruction after World War II (OECD 2008, Noaksson/Jacobsson 2003: 11ff., Wolfe 2008). Thus, the OECD's mission is primarily economic, i.e. to "help governments achieve sustainable economic growth and employment and rising standards of living in member countries while maintaining financial stability, so contributing to the development of the world economy" (OECD 2008: 9).

The OECD is a hybrid between an expert and political organization. As an informant put it, it "is intrinsically a political organization but I see the advisory function, the think tank function, this information and advisory function very much in the foreground" (v: 308-310). Dostal captures the main features of the OECD as an expert and political organization in a nutshell:

"The OECD has features of an international civil service, a think-tank and a shared state apparatus, and is based on the broad representation of advanced industrialized countries. (…) Its internal structure is intergovernmental, with a ministerial council as the most important formal decision-making organ and permanent national representatives working on policy proposal alongside the organization's professional staff" (Dostal 2004: 446).

The following section is dedicated to unfolding the meaning of Dostal's solid characterization.

2.1.1 Policy Forum

The OECD is "a permanent conference of governments" (Oborne 1999: xiv), a policy forum to exchange policies between Member States. It describes itself as a "unique forum where the governments of 30 market economies work together to address the economic, social and governance challenges of globalization as well as to exploit its opportunities" (OECD 2008: 7). It "provides a setting for reflection and discussion, based on policy research and analysis that helps governments shape policy that may lead to a formal agreement among member governments or be acted on in domestic or other international fora" (ibid.: 13). The OECD

does this by comparing policy experiences, seeking answers to common problems, identifying good practice and co-coordinating domestic and international policies (c.f. ibid. 7).

In the field of biotechnology, an interview partner likewise described the OECD as „a policy forum on biotechnologies" (iv: 5-6). The OECD also played this role in international xenotransplantation policies. As one interviewee recalled, it brought together policymakers and researchers from academia and industry to exchange knowledge and to learn about recent developments in research and policy making:

"It was an area where the knowledge base seemed to be concentrated primarily in the US and the UK and there was a need to understand how the private sector also was moving around it. (…) So these are also ways for government to dialogue with industry, and understand what is happening; dialogue with science, dialogue with academia, dialogue with industry and it becomes a policy forum. And it can become also a foresight forum. So this was a mixture of foresight forum and of policy forum" (iv: 262-268).

This OECD expert described the learning effects of such an exchange between civil servants and experts: “suddenly (…) you have dialogue and you start to compare the practices that you´re having around in all the various countries" (iv: 453-460). Another respondent described how this mutual learning process by comparison also had an impact on national policies: "The OECD is a policy advisory organization in which experts from nation states meet to present examples of their policies to others and by this mutual presentation, work out insights und carry them back again and possibly say: 'well, they do this a bit better, they have found a solution to that problem'. To work, in a way, to advise policy and reforms" (vii: 107-111).

The New York Workshop on xenotransplantation, organized by the OECD, worked in the same way: "it brought together the policymakers with the experts and with, what are called, non-government-organizations" (x: 39-42). This "information exchange” was important “so that we could have a common understanding of the risks, the ethical issues and the potential benefits" (x: 86-88). For this interview partner, the benefit of the OECD’s contribution consisted of acting as such a policy forum on xenotransplantation policies nationally and internationally.

2.1.2 Expert Organisation and Think tank

The OECD was often characterized as “think tank” (v: 23) or “policy think tank” (ix: 3), which allows Member States to exchange strategies on economic policy (ii: 49-52), or as "a coordination organization in economic policy" (v: 5-6, 144). The OECD was also frequently described as an "expert organization" (iii: 171, 633-634) or "an expert organization addressing governmental structures" (ii: 5-6) that answers questions it is asked (c.f. ii: 26-27).

The OECD fulfills these functions with its Secretariat staff of about 2.000 "experts" (v: 147) of "international civil servants" (v: 141), the "backbone" of the organization (v: 134). As one interviewee put it, the Secretariat is the "vitally important machinery" of the OECD, which drives and facilitates much of its very technical and specialist work (c.f., x: 150-155).

The majority of the Secretariat's experts are economists but there are also social and natural scientists as well as engineers (interview ii: 13-16). These do not deal with typical public administration but provide "intellectual capital" (v: 143-144). They are well connected with international expert networks in academia, policy making and private research in which they have been trained and have worked. However, not only members of the Secretariat staff are experts in their field, Committee Members, who have been working in their national ministries for years on a particular topic, can be considered as experts in their own right as well (vii: 115-122). Both types of OECD staff contribute to the OECD's role as an expert organization.

This close network of experts, consisting of Secretariat experts and national civil servants, also carries a risk. There is, according to one civil servant, a strong basis to claims that the OECD is an ivory tower in which scientists and experts talk to one another and that OECD documents are primarily read by this limited group of people (vii: 83-84).

2.1.3 Policy Advisor

The OECD's mission is not restricted to being an expert organization, it has a particular addressee; it is an "advisory organization to politics" (vii: 94-95), an "expert organization embedded into public administration and politics" (vii: 100). It is not just another research organization, but, as an interview partner explained, a pragmatic organization that tries to find out what projects are practical, feasible and fundable for politics (vii: 101-102). The OECD differs from ordinary research institutions because of its close intertwinement with Member State administrations. The Secretariat regularly discusses its research with civil servants from Member States (iii: 157-162). A respondent emphasized the importance of this constant mutual exchange:

"It is most essential, (…) that they not only do research, but that twice a year there is a Committee in which these papers are presented, discussed and people are simply invited to give their opinion, what they think, what the national experiences are, and so on; and by that [process] the accumulated knowledge is also fed back. So, I am now talking a little bit about the way that it should be" (iii: 160-168).

Another informant used an economic metaphor to describe the relationship between policymakers and OECD experts, distinguishing between consumers of advice – i.e. government bureaucracies - and suppliers – i.e. the Secretariat. Consumers put topics on the agenda and use the experts' work (ii: 6-7). Another civil servant used a similar metaphor

and described the Committees as "customers" or "clients" of a respective Directorate (v: 202-203).

2.1.4 Political Organization

For several reasons the OECD is not simply a remote expert organization and policy advisor, but also and intrinsically a highly political organization:

First, the OECD is not only an exchange platform for information, it is also an organization "where political decisions are made" (interview i: 99). Since these are made in sensitive areas, various governmental and non-governmental actors try to influence them at the domestic and international level. Although the OECD only uses soft regulation for the most part, its recommendations and guidelines nevertheless have an impact on national policies. OECD documents can justify or discredit domestic politics and therefore become ammunition in domestic and international political debate. Member States can decide to transform recommendations and guidelines either into national law or not (ix: 43-49). Moreover, there is a certain peer pressure to follow policies (e.g., Noaksson/Jacobsson 2003, Marcussen 2004, Mahon/McBridge 2009).

Second, the OECD is inherently an "etatist" organization; its members are national governments, and it is also governments who are addressees of the OECD's advice (ix: 38-40).

The OECD therefore, and this is the third argument, has an "international governance structure" (v: 155), which corresponds with, is derived from, and closely linked to government structures and hierarchies in Member States. In the words of a respondent, "the OECD is nothing other than (…) a supranational bureaucracy" (i: 79-81). Hierarchies in domestic public administration, e.g., are reflected in the OECD's structure. There is a particular order in which civil servants of particular seniority are delegated to OECD bodies. Ministers participate in the annual Council meeting or in Council meetings for special ministries; ambassadors participate in regular Council meetings; their deputies participate in the Executive Committee; civil servants of various seniority levels from relevant ministries participate in Committees and Working Groups (iii: 032-052). Specialists, who are experts in the topics discussed, participate in the most basic working groups; the Task Forces (see 2.3.2).

Fourth, reports and documents must pass through the lengthy and complicated process of the OECD's internal governance structure. Once they pass "declassification" (see 5.1.4.), they are official OECD documents and "very close to governments". This close interaction between state bureaucracies and experts increases the chances that policy advice is actually implemented because it has been negotiated with, and is directly addressed to governments: "there are *layers and layers* of oversight *but* the strength of something like this

is that once you come out with something and it is approved at the highest layer then it is out there, it is in government, straight in government, which is not the case, for example, with the World Health Organization which hires, you know, experts but they don´t have the sort of bureaucratic layer with government people" (iv: 136-140, emphasis in the original). Negotiation and declassification confers an official status onto OECD policy papers. As an informant put it, "all of these papers (…) are negotiated. This means that this is a negotiated final report that countries have agreed to and they approve for declassification" (iv: 145-149).

Finally, the OECD is highly political because of its framing as an expert organization and the intrinsic ideology of this claim. According to a civil servant, the OECD gives itself the image of an apolitical and essentially science and evidence based organization and by doing so is highly political, since the intrinsic assumptions and ideology of a certain kind of expertise are rarely discussed. This has been shown for economic policy (Noaksson/Jacobsson 2003) but also holds true for xenotransplantation policy, which provides privileged access to scientific experts, government actors and industry representatives and the application oriented questions these groups address.

2.2 Different Policy Issues

Given its economic point of reference the OECD deals with a remarkably broad range of issues. OECD Directorates, Committees, Working Parties and Task Forces are concerned with almost all policy areas with the exception of defense and culture (ix: 35-36). Because of its mission in economic policy, the OECD focuses on all of these policy fields from an economic perspective (ix: 35-36). However, there is a hierarchy of policy fields because some areas are more central concerns to the organization than others. Interview partners repeatedly referred to the regular economic surveys of Member States as the OECD's core tasks (iii: 093-097). As a former OECD expert explained: "that's virtually the core of the OECD, the core mandate is to write reports twice a year on the economic policy of OECD countries and to advise governments, (...) to give guidance; that's the core task" (i: 54-58). These economic country reports are the OECD's "standard and flag ship" activities (v: 64) and belong to its most prestigious core mission. Macroeconomics, according to a senior diplomat, is at the center of OECD interest (ix: 13). Whether topics are considered important and are therefore discussed between Member States more deeply and with more emphasis depends on their proximity to economics and core state interests (v: 83-87). Biotechnology in comparison to economics is a rather new and highly specialized issue with relatively little political relevance from the OECD's perspective. It is a "boundary area", which was never on the agenda at the highest level of Council meetings (ix: 17-23). However, the status of a topic can significantly change as the examples of the Program for International Student Assessment (PISA) and science and technology policy show. Both topics progressed from a relatively marginal position to the center of OECD's activities.

2.3 Organizational Structure

The formal internal governance structure has been exhaustively described (e.g, OECD 2008). The following section will therefore be limited to a short description of the formal structure. The OECD is composed of several organizational bodies that serve different functions, i.e. the Council, the Committees and their sub-units (Working Parties and Task Forces) as well as the Secretariat.

2.3.1 Council

The Council is the OECD's highest decision-making body. It is staffed with one permanent representative per Member State and one representative of the European Commission. Permanent representatives are diplomats and act as liaisons between the OECD governance structure and their national governments. Once a year the Council meets at the ministerial level to "discuss key issues and set priorities for OECD work" (OECD 2008: 11). Among other topics this meeting decides on the budget, which amounts to around 340 Million a year (ibid. 12).

2.3.2 Committees, Working Parties, Task Forces

Other bodies within the OECD are the so-called Committees and their sub-divisions, the Working Parties and Task Forces. Member State representatives meet in about 200 of these Committees, Working Groups as well as Task Forces, where they discuss policy ideas and review progress in specific policy areas. Each year about 40,000 senior officials from national governments participate in meetings of these OECD bodies (c.f. OECD 2008: 11).

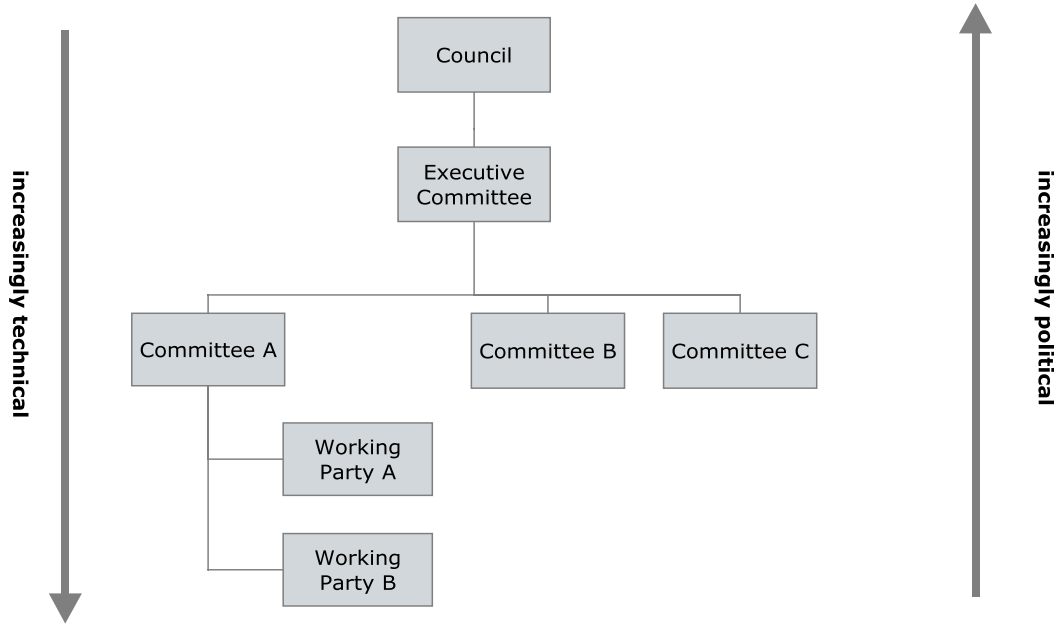
There are different kinds of Committees. Standing Committees are the OECD's political superstructure (vii: 222); they consist of, e.g., the Executive Committee, the Budget Committee, the External Relations Committee, the Committee on Public Affairs and Communication. Other Committees deal with specific topics such as, to name only a few, economic policy, environment, development, trade, agriculture, education, and transport. Committees are composed of national delegates, which are either civil servants of the responsible national ministries or experts from outside government, who have been nominated by Member States, either because of the particular specificity of a topic or because the responsible civil servant is simply too busy (ii: 9-13, iii: 19-25, iii: 21-22). The Committee relevant for OECD xenotransplantation policies was the Committee for Scientific and Technological Policy (CSTP).

In order to carry out the more specific work, Committees establish so called Working Parties. The latter are staffed with civil servants and experts, which act as "peers" of the Directorate's experts (v: 297-305). The responsible Working Party for xenotransplantation was the

Working Party on Biotechnology and the Working Party on Human Health Related Biotechnology (WPB, see 2.3.3).

There is yet another level of bodies: the so-called Task Forces. They are established informally for a fixed period of time and are exclusively composed of experts. In the case of xenotransplantation, such a Task Force or Informal Expert Group was established.[2]

Figure 1: Representation of Political and Technical Aspects in OECD



(Source: Interview vii)

Councils, Committees and Working Parties differ in regards to types and seniorities of their members. The Council is a purely political body composed of ambassadors, who have very little knowledge about the specifics discussed in Committees and Working Parties. They deal with the general governance of the OECD as well as fundamental and highly political decisions. Committees are composed of a mixture of experts and civil servants. They are the bodies, which, e.g. decide on specific work programs and declassification of documents. But they still mostly lack the specific expert knowledge about the issues discussed in Working Parties and Task Forces. Working Parties and Task Forces are almost entirely staffed by experts (v: 11-15). This stratification is also reflected by the kind of Secretariat staff attending meetings; as a rule of thumb, meetings of Task Forces are attended by staff members, Working Party and Committee meetings by department heads, and Committee meetings by

[2] The naming of this group is heterogeneous in documents. In one document it is called “Informal Expert Group”, in the official OECD workshop report it is called “Steering and Expert Group for the Preparation of the OECD workshop New York ‘98”.

chief department heads (ix: 200-204). Thus within OECD bodies there is a direct relationship between politicization and hierarchy (c.f. Figure 1).

2.3.3 Working Party on Biotechnology

An example for internal differentiation that is connected to the constant growth of topics within the OECD (see 5.1.1.) is the Working Party on Biotechnology (WPB). It was created in March 1994 (OECD 1995) and reports to the Committee of Science and Technology Policy (CSTP).

The WPB itself has a much broader remit than human health related biotechnology and included industrial and environmental aspects of biotechnology. Its original objective was: "to keep under review and advise upon science, technology and innovation issues in biotechnology, with a view to assisting the development of its safe and effective use, by inter alia, encouraging the international harmonization of science-based principles and practices, and facilitating international scientific and technological collaboration and exchange".

In 1998 this objective was reformulated and particularly recognized health care in its mission:

"the Group will advise upon emerging policy-relevant issues of science, technology and innovation related to biotechnology, with a view to assisting the development, application and diffusion of products, processes, infrastructure and services which, through industrial production, environmental protection and health care, will contribute to sustainable economic growth and development, and human welfare. This should be achieved by: encouraging the international harmonization of science-based policies, principles and concepts; facilitating scientific and technological co-operation, capacity building and exchange; and informing and assisting the work of policy-makers in Member countries" (OECD 1998: 316).

The Working Group on Human Health Related Biotechnology developed from the WPB and was formally established in 1995. It deals, as can be concluded from its name, specifically with the human health related issues of biotechnology (c.f. iv: 7-10). In 1997 the Working Group formed another sub-unit, a Task Force specifically addressing xenotransplantation policies. This structure was chosen because the establishment of a formal body would require Council authorization; in contrast such a lengthy procedure was not needed for creating a temporary informal expert group (c.f. iv: 40-44).

2.3.4 Secretariat

Since Committees meet only twice a year and their members are mainly occupied with their tasks as civil servants in their home countries, additional expert staff is necessary to carry out actual research and analysis. This everyday work is carried out by the Secretariat and its divisions, some of which are called Departments, others Directorates. One of them is the

Directorate for Science, Technology and Industry (DSTI). Directorates can become relatively big. Thus, they are subdivided into smaller divisions, which are again further divided into smaller sub-units. Due to these divisions, problems common to big organizations arise, i.e. lack of communication and problems of dealing with cross cutting issues. There is also a particular informal stratification between Directorates according to the topics they deal with (see 2.2). Because of its economic reviews, the most powerful and prestigious is the Economics Department (i: 53-57). In comparison, there are also very small unit. For example, the biotechnology unit is only staffed with three people (iv: 213-214).

The Secretariat has a total staff of about 2,500 people (OECD 2008: 12, see also 2.1.2). It “parallels the work of committees with each directorate servicing one or more committees, as well as committee working parties and sub-groups” (OECD 2008: 14). In practice, a sub-unit of a Directorate may "serve" several Committees (v: 172). In this sense, a member of Secretariat staff might talk about a Working Party he/she is working for as "my Working Party" (i: 123-124). Committees and Directorates come together every six months to present and discuss draft documents. Thus, OECD work is done through interactions between experts and civil servants (viii: 50-51). This also helps OECD staff to validate their data and findings.

3 OECD Xenotransplantation Policies

This section provides an overview of the development of the OECD's xenotransplantation policies (c.f. Table 6). It starts with a short description of the OECD's interest in biotechnology and xenotransplantation and continues with a narrative of the policy development from a single-authored background paper to a joint OECD/WHO document on xenotransplantation. The chapter ends with a summary of the main features of OECD xenotransplantation policies.

Table 1 Timeline and overview of landmark developments

1996	Policies paper "Advances in Transplantation biotechnology and Animal to Human Organ Transplantation (Xenotransplantation)" is published
25.3.1997	Meeting of the Working Party on Biotechnology to prepare the New York Workshop
1997	Informal Group on Xenotransplantation
18.-20.3.1999	New York Workshop on Xenotransplantation
30.11.1999	Framework for Cooperation of the OECD/WHO
1999	Report on the International workshop on Xenotransplantation
4.-6.10.2000	OECD/WHO Consultation on Xenotransplantation Surveillance in Paris
2001	Compilation of regulatory developments in xenotransplantation in OECD Member States
2002	OECD Participation in WHO/Health Canada Internet Discussion Group

> "The question for many researchers today seems to be, not how, but *when*, xenotransplantation should advance to the clinical arena" (OECD 1996: 14, emphasis in the original).

> "What we are trying to do is nurture an evolving technology and at the same time be careful because there are inherent risks. And do I have the right answer? I don't know that" (Jay Fishman in Shaikh et al. 1998: 247).

3.1 OECD interest in biotechnology and xenotransplantation

The quotations at the beginning of this chapter present the aim of OECD's xenotransplantation policy in a nutshell, i.e. xenotransplantation itself is not put into question; however, it is made clear that it should be developed in a framework that safeguards the protection of public health in a situation of uncertainty. This framework was developed by experts, policymakers and industry representatives.

The OECD's involvement in biotechnology as a policy area started in the mid-1980s with "a series of reports on scientific principles and concepts relevant to safety assessment, and socio-economic and other policy issues" (OECD 1996: 3). In the 1990s the OECD started to become active in health care related biotechnology and dealt with issues such as live vaccines and gene therapy.

The OECD considers biotechnology as a relevant topic for its own work because, as a civil servant put it, "it is one of the strongest sectors of high technology and of enormous potential for growth and employment and future employment" (iv: 251-253). In the context of biotechnology, the OECD was concerned about competitiveness, trade, trade barriers, and heterogeneous policies that would present "a risk of incoherence in the international environment" (iv: 255-256), as well as issues of skills and training. The OECD frames biotechnology from an economic perspective, and, as an OECD expert explained, according to its economic agenda: "so all of this is economics! All of this puts it square into the OECD mandate of competitiveness, of trade, of skills and training, of future potential, of high technology sectors " (iv: 257-260). In this way xenotransplantation was also considered a topic of high economic potential.

Interest in xenotransplantation developed from previous work of the WPB on gene delivery systems and gene therapy and from a white paper, in which WPB members formulated research needs (c.f. iv: 22).

The initiative to investigate xenotransplantation came from the WPB and was promoted by several Member States (OECD 1996: 3). It was motivated by the OECD's "interest in leading edge technologies (and their policy implications), and drawing attention to the recent

significant biotechnological developments in the field of transplantation" (ibid.). The initiative to investigate xenotransplantation was proposed by the UK Department of Health, Health Canada and the US Office of Science and Technology Policy. The strongest support and push came from the US and the UK, "the leading countries in terms of research". Both countries "were very much in favor to bring this forward and to look at it" (iv: 60-63). From the perspective of another civil servant, Canadian representatives were particularly interested in creating a policy forum in order to discuss xenotransplantation policy options in an international context (x: 194-196). This proposal was also driven by a concern about uncontrolled clinical trials, which might take place in developing countries and potentially pose a global threat. Canada, the US and the UK were the "lead countries" (ix: 14), that wanted to put the topic on the agenda. For that, however it had to meet certain criteria developed by the WPB, such as "added value that the OECD can bring", an "international dimension" of the problem, and connection to the "strength of the OECD" (x: 19-21). Moreover, necessary funding had to be made available. Xenotransplantation was finally selected as a topic because it was interesting for a number of Member States (x: 23-34). The Secretariat was asked to write a scoping paper (iv: 96-100), the background paper on xenotransplantation, published in 1996.

3.2 Background paper

OECD work on regulating xenotransplantation became visible for the public in 1996 with the publication of a 28 page "background paper" for "general distribution" titled "Advances in Transplantation biotechnology and Animal to Human Organ Transplantation (Xenotransplantation)" (OECD 1996: 3). The single-authored paper is based on relevant international literature and was written to prepare an OECD workshop on xenotransplantation in New York, which was planned for 1997 and actually took place in December 1998.

The paper was written by Dr. Elettra Ronchi, a trained neuroendocrinologist, who worked in in the Biotechnology Unit of the OECD Directorate for Science, Technology and Industry (DSTI) as "Co-coordinator Health and Biotechnology Activities". She is the key person responsible for xenotransplantation policies within the DSTI and dealt with the topic until the OECD stopped its activities on xenotransplantation in 2001.

The background paper starts by sketching the history of transplantation, pointing at early failures and the fact that transplantation became an accepted routine practice (ibid. 5).[3] It identifies organ shortage as one consequence of this success and substantiates this shortage with figures from the US, the UK and France (ibid. 5 ff.). The document describes mechanisms of organ rejection, explains hyperacute rejection, delayed xenograft rejection and chronic rejection as well as methods to prevent these effects (ibid. 9f f.). Turning to

[3] For a short summary of this paper see Paslack 2008, 116-118.

xenotransplantation, the paper provides a short early history of this approach starting with the 1960s and later turning to more recent developments including the UK based firm Imutran's announcement that it would start clinical trials involving humans in 1996. Concluding from this research the paper defines what can be called the central framing of the OECD's approach to xenotransplantation: "the question for many researchers today seems to be, not how, but *when*, xenotransplantation should advance to the clinical arena" (ibid. 14, emphasis in the original).

The OECD takes a pragmatic approach towards xenotransplantation. It does not ask, as many other national policy documents did, whether xenotransplantation should be further developed at all, but poses several questions which it claims should be answered before clinical trials could start: "under what conditions should experimentation proceed, and what is the minimal goal of the clinical application of xenotransplantation? Are we applying premature use of unproven procedures in fellow humans? Is xenotransplantation going to provide primarily 'a bridge'? Is (successful permanent xenotransplantation) an acceptable and reasonable target?" (ibid. 14 ff.)

The OECD paper discusses pigs and baboons as potential donors. In regards to pigs the paper explains which organs might be used, refers to current research in Sweden and the UK, points at the problem of rejection and strategies to overcome them, and finally poses two questions. First, whether, provided that rejection mechanisms are solved, pig organs might be "physiologically capable of supporting prolonged human life" and, second, which precautions might be necessary "to avoid the transfer of porcine pathogens to the immune suppressed human recipient" (ibid. 16). The paper concludes that, "if porcine tissue is to be transplanted into humans, guidelines for stringent microbiological programs must be developed" (ibid.). Although the paper addresses the need to breed pigs under specific pathogen-free conditions, it does not raise ethical questions (e.g. animal welfare) connected to this approach in this section.

In contrast, ethical issues are addressed when the policy paper discusses baboons as donors. Baboons could "supply organs on a smaller scale than the pig" but are better immunologically compatible with humans (ibid. 17). Possible organs could be the liver and heart, although the latter could only be an option for infants and small children because of its smaller size. As with pigs, the paper reports that there would be a "pressing concern" of transmitting viruses to humans, the behavior of which "in the immunocompromised host remains unknown". Besides practical reasons, such as long pregnancies and small numbers of offsprings, the main objections to the use of baboons as source animals are ethical. The "close evolutionary relatedness (of primates), creates concern over the ethics" of using them as source animals (ibid. 18). The paper concludes that "to breed primates on a large scale for organ donation would be contrary to the currently accepted guidelines in various countries" (ibid.).

Concerning the regulation of xenotransplantation, the paper shortly mentions work being done by the WHO, the US as well as the UK.

The document also discusses economic aspects of xenotransplantation, listing mainly US based firms active in the field and pharmaceutical companies developing immunosuppressive drugs (ibid. 19ff.). The report concludes that the field "attracted (…) significant private investments" (ibid. 21) and transplantation itself "is estimated to produce a saving of 63 per cent over total medical expenses for a renal patient when compared to life-long dialysis treatment" (ibid.). Nevertheless "xenotransplantation will most likely not lead to a reduction of average costs" of transplantation. "The costs of the operation will be the same, except that the organs will have to be purchased" (ibid.). In addition there would be costs for "monitoring xenograft recipients for evidence of diseases" (ibid.). However, to use xenotransplantation for bridging "will most likely increase the overall direct costs of transplantation, and may be, in the long term, much less cost-effective" (ibid.).

In its concluding section, the report claims that xenotransplantation is connected to issues of global concern, which should be dealt with in international fora. It provides the central framing of this report, i.e. safety issues. The paper refers to national guidelines, which "suggest a cautious attitude toward xenotransplantation, in particular when primates are involved" (ibid. 22). Pointing at recent outbreaks of ebola, hantavirus and dengue fever, the author perceives "emerging diseases as a global issue" and therefore a need for international harmonization of "guidelines on medical and research practices on xenotransplantation". The WHO would be an ideal organization for such an undertaking.

Without discussing them in further detail, the paper lists a number of ethical and socioeconomic questions, which would be best addressed by UNESCO and the OECD, such as: animal rights, alternatives, prevention, impact on health care systems, impact on peoples' readiness to donate organs and patenting of genetically modified animals. The paper emphasizes the need for urgent action and advocates international cooperation to "ensure that adequate guidelines are promptly in place to enable effective review of clinical evidence and to prevent possible public health hazards, at the same time allowing medical progress and equitable technology transfer" (ibid.).

This first publicly available OECD document on xenotransplantation delineates the organization's approach to this new technology:

- The OECD primarily frames xenotransplantation in terms of the problem of organ shortage, sound science and economic considerations.

- The issue of a moratorium is not addressed. Xenotransplantation is framed by technological determinism: it is not the question whether, but when it will happen. Therefore the main question is not whether this technology will or should be

developed at all – i.e. the then pending question of a moratorium, which was discussed in many countries and the Council of Europe -, but under what framework it could be put in place most safely.

- Ethical issues are only mentioned in the context of using baboons or primates, not regarding the use of pigs. Other ethical questions are only listed and not discussed in any detail.

3.3 New York Workshop

After discussing the background paper, the WPB nominated an “Informal Expert Group” to organize an international workshop on xenotransplantation. The WPB did not only face the challenge to find out what the policy agenda was but also the current state of xenotransplantation research: they "realized that there was a need to look at where the science was going. The policy agenda was not clear when we first started because the science was not yet clear to many" (iv: 63-65).

This Informal Expert Group met in March 1997 in Paris. It was chaired by David Harper, Chief Scientist at the UK’s Department of Health and Chairperson of the WPB as well as of the Working Party on Human Health Related Biotechnology. The group included Member State delegates[4], Elettra Ronchi from the Biotechnology Unit, one representative each from the WHO and the New York Academy of Science (NYAS) - the host organization of the workshop – as well as two industry representatives[5] (OECD 1999: 102ff.). There were no representatives of patient organizations or NGOs in the group. The informal group discussed workshop objectives - including title, workshop aims, questions to be addressed, speakers -, the outline program, its format, and last but not least, the workshop’s funding.[6]

The New York Workshop was held from 18-20.3.1998. It was titled “International Issues in Transplantation Biotechnology, Including the Use of Non-human cells, Tissues and Organs” and was co-organized by the OECD and New York Academy of Science. It was co-financed by the Governments of Canada, Germany, Switzerland, the UK and the European Commission and supported by the WHO and US Public Health Services agencies.

3.3.1 Participants

The New York Workshop brought together participants from 17 OECD Member States, three Non-Member States and the EU Commission (OECD 1999: 3). Participants were repeatedly addressed as “experts”, “delegates” (ibid. 3; Fishman 1998: x), and “leading experts and

[4] Delegates came from Austria, Canada, Germany, Italy, Japan, Korea, Spain, Sweden, Switzerland, the UK, and the US

[5] As invited experts representatives of Imutran and Novartis were present.

[6] About the importance of co-financing for putting issues on the agenda within the OECD see chapter 4.

representatives from OECD member countries" (OECD 1999: xix). This indicates the character of the meeting as a policy forum organized for representatives from national governments and international organizations as well as public research and private industry.

In its official publication the OECD lists ca. 50 participants (OECD 1998: 89ff.). The Islet Foundation, a patient organization lobbying for diabetes patients that participated in the workshop, published an unofficial record on the Internet (Islet Foundation n. d.). A combination of these two lists results in an attendance of 138 people. Participants were nominated delegates of OECD Member States (iv: 336-347).

Table 2 Participants per Country

Country	Number of Participants
USA	48
UK	13
Switzerland	11
International Organizations	8
Canada	9
Sweden	7
Germany	6
Netherlands	6
France	4
Italy	4
Israel	4
Spain	3
Austria	2
Belgium	2
Norway	2
Japan	2
Czech Republic	1
Finland	1
Greece	1
Cameroon	1
Oman	1
Portugal	1

(Source : OECD 1999 ; Islet Foundation n. d., own compilation)

In terms of country participation, the workshop was dominated by countries with a particular interest in xenotransplantation, either because of their own research activities or because they hosted industry active in xenotransplantation research (see Table 7). The number of US participants was by far the highest with 48 participants, followed by the UK (13), Switzerland (11), Canada (9), Sweden (7), Germany and the Netherlands (6 each).

Looking at the type of participating organizations (see Table 8), the largest group was policymakers from national and international organizations (51 participants). Participants from research in hospitals, universities, national research institutes and research funding organizations added up to 50 people. Industry participation was also a strong group with 26

representatives.[7] Seven participants came from Technology Assessment organizations, though in the case of Sweden it is hard to distinguish clearly between TA and policy making. Only four participants came from NGOs, three of them from patient organizations and one from an animal welfare organization. As can be seen from Table 8, according to the type of organizations the workshop was dominated by expert, government-and industry involvement with little participation from NGOs and the public.

Table 3 Participants per Type of Organization

Type of organization	Number of participants
National and international regulatory authority	51
Research at hospitals, universities, national research institutes; research funding	50
Industry	25
Technology Assessment	7
NGO	4

(Source: OECD 1999 ; Islet Foundation n. d., own compilation)

3.3.2 Format

With formal presentations and alternating plenary and parallel sessions, the workshop followed the regular model of a scientific conference. Sessions included formal presentations, which were followed by discussions as well as question/answer sessions. Uncommon for a scientific conference and more common at policy events, the workshop had a general rapporteur and a rapporteur for each of the two days.

An introductory section, including welcoming addresses by the organizers and a keynote speech by molecular biologist and Nobel laureate Joshua Lederberg set the stage for the meeting. The introduction was followed by two parallel sessions on “Infectious Disease Risk” and “Safety and Quality. The Challenge of International Surveillance”. This was again followed by a second set of parallel sessions, one on “Immunology and Xenografts: Science and Perspective”, the other on “Social, Legal and Ethical Aspects”. Session IV was dedicated to an “International Policy Forum” and the concluding session on “Policy considerations”. During the last session the general rapporteur encouraged and replied to comments from the audience.

The public was addressed in a press conference in which representatives from the OECD, WHO, national regulation authorities and researchers provided short statements and answered questions of journalists (Shaikh et al. 1998).

[7] This group includes 20 participants from the US, 4 from Switzerland and one each from UK and Canada.

3.3.3 Objectives and Issues

As can be seen from the type of audience, the workshop's aim was to get information about the state of the art in xenotransplantation research and related areas as well as national and international policy making in order to facilitate coordinated international xenotransplantation policies; this goal was formulated in the opening speech by WPB Chairman David Harper. In his words, the workshop was intended to "guide OECD member countries towards international coordination and the establishment of coherent international policies and regulations on xenotransplantation" (Harper 1998: xix). It should "discuss and formulate an OECD opinion on current developments on xenotransplantation to be condensed in a series of policy considerations for OECD member countries" (ibid.). The OECD wanted to build on existing experiences of experts and policymakers. David Harper expressed this goal by addressing the expert audience: "many of you here belong to advisory groups or committees that have or are about to formulate guidelines on this new technology. (…) We wish to build our discussions on your experience" (ibid.).

Following the framing in the 1996 background paper, the WPB Chairman contextualized xenotransplantation again by portraying transplantation as an accepted practice, which became a "victim of its own success" (ibid.). He asked the audience several questions, which the members of the Informal Expert Group already had agreed upon beforehand in a preparatory meeting (ibid. xx ff.):

1. What is "the actual burden to society of diseases where xenotransplantation may have a role"? What alternatives exist to alleviate organ shortage?

2. "What are the available or possible alternatives derived from recent technological advances"?

3. What are the "xenozoonotic risks" and "which public health tools are currently available or are being developed to prevent the risk of inadvertent transmission of infectious agents into xenotransplant recipients"?

4. Which "informative analogies" can "be drawn between gene therapy and xenotransplantation"?

5. Which "public health tools are currently available or being developed to reduce or eliminate the risk of inadvertent transmission of infectious agents into xenotransplantation recipients"?

6. What are the "features of a compatible international framework to detect, identify, monitor, evaluate, and manage xenozoonotic risks"?

7. How can international organizations such as the OECD "enable the establishment of effective frameworks and infrastructures" necessary for the clinical practice of xenotransplantation?

These questions would later guide the workshop conclusions published in a report (OECD 1999: 73).

Jay Fishman, co-editor of the records of the New York Workshop and expert in infectious diseases related to transplantation, and his colleagues framed the workshop's objective slightly differently (Fishman et al. 1998: x):

1. "to provide background information concerning progress and controversies in the field of xenotransplantation in the areas of immunology, infectious disease, animal husbandry, and medical ethics and public policy;

2. to discuss those issues of particular importance to the development of international strategies and a regulatory framework for the protection and benefit of public health; and

3. to identify issues and approaches relevant to developing regions."

The question whether xenotransplantation should be further developed or whether a moratorium should be imposed was not an explicit question of this workshop. Although a few presentations shortly mentioned the issue of a moratorium, most papers were clearly oriented downstream and instead addressed questions on how to put xenotransplantation into practice safely.[8]

In other words, the workshop was dominated by the question of how to put xenotransplantation into practice. Of the 39 formal presentations[9] most were dedicated to the

[8] In his introduction David Harper only mentioned the issue of a moratorium when he referred to different positions towards xenotransplantation held in OECD Member States and mentioned the Council of Europe's debate, which would call "on a hold on clinical trials until further research shows that the technology is safe and offers real benefits" (Harper 1998: xxi). André LaPrairie and D. Brodie, two civil servants from Health Canada, also addressed the issue of a moratorium and reported that the Canadian National Forum on Xenotransplantation agreed not to recommend a moratorium because "a moratorium is not the best medium for controlling research behavior in that it can pre-empt proactive public discussion and remove the issue from the public's mind" (1998: 174).
Abdallah S. Daar, a surgeon from the Sultanate of Oman, addressed the question of a moratorium: "some scientists active in xenotransplantation research have gone so far as to argue for a moratorium in the United States because of the need to involve the public in more detailed discussions before embarking on clinical trials" (Daar 1998: 230).
In a final press conference, Jay Fishman explained why he was no longer in favor of a moratorium. His intention for a moratorium was to discuss the "potential for third-party risk" and to have "public involvement in oversight". In his opinion, this discussion has been led by the US Public Health Services, which also developed " an oversight committee to address the concerns of laypeople, lawyers, ethicists, other individuals in addition to scientists who have relevant opinions in this area" (Shaikh et al. 1998: 239).

[9] Not counting the rapporteur's addresses in the sessions.

related areas of risk of infection (6 papers), necessary surveillance (10 papers) and appropriate policies (4 papers). Five papers addressed issues of allotransplantation, i.e. broadly speaking the transplantation of human organs into humans and the organisation of organ procurement. Another five papers addressed questions of immunology. Three papers dealt with public perception and the other two with the development of xenotransplantation and animal welfare respectively. The rest of the papers contained opening and concluding remarks (4 papers).

As already mentioned, the OECD did not ask the question whether a moratorium would be necessary or not, but framed xenotransplantation as a development that eventually is going to happen and which, in order to be safe, should be regulated. An example for this is the paper by Fishman and his colleagues. They also did not address the issue of a moratorium explicitly but instead defined the goal of xenotransplantation regulation as promoting the safe development of this technology: "the goal of regulatory efforts must be to assure continued progress in the field while exerting a maximal effort to assure clinical efficacy and public safety" (Fishman et al. 1998: xi). Fishman et al. advocated continued research as well as flexible and "dynamic" regulation, which could be made more or less stringent according to the development of research and relevant research results.

The following section will not look into the details of the presentations but will focus on the way in which public perception of xenotransplantation, and potential involvement of the public, were discussed.

3.3.4 Public Involvement

Researchers and policymakers took different approaches on how to conceive of and involve the public. These approaches can be categorized into three types: the first two - *involvement as helplessness* and *involvement as public relations* - perceive the public as an uninformed outsider, whereas the third - *involvement as participation* – attempts to include the public into regulation.

3.3.4.1 Involvement as Public Relations

A first approach to public involvement that perceives the public as outside of research and regulation is *involvement as public relations.* This approach tries to anticipate public reaction and sensibility. It is well aware of public attitudes and it tries to avoid pitfalls. The aim is to persuade the public of one's cause. Involvement with the public is perceived as achieving acceptance. As Tallacchini put it, public involvement is only acknowledged "instrumentally, namely to provide evidence and support for xenotransplantation from the public" (Tallacchini 2007: 357)

Abdallah S. Daar's presentation provides an example of this approach. He stated that "while it seems foolish to predict the public's response to xenotransplantation, an attempt is nevertheless worth our while, if only to identify and try to avoid pitfalls and achieve the desired response" (Daar 1998: 223). Previous experiences shall "help us draw conclusions about what to avoid" (ibid.). Public reaction should be predictable and is perceived as being based on certain factors. These are: "(1) past experience; (2) studies of attitudes; (3) knowledge of cultures; and (4) certain additional factors predicated on perceptions (e.g., on the adequacy of the scientific base, public education, honesty, etc.)" (ibid. 224).

According to this approach public confidence is to be gained and carefully nurtured. Xenotransplantation has to be "sold" (ibid. 228) to the public and "how the public is 'sold' the idea of xenotransplantation will also likely affect the exact response" (ibid.).

Abdallah Daar reiterated previous clinical xenotransplantation experiments and facts that contributed to public awareness. He referred to the public via opinion polls as a survey public. However, for methodological reasons he was not uncritical of existing studies that had used questionnaires and focus groups. How do you address problems, which are not known? What do respondents know about the details of xenotransplantation? He described several scenarios, which would negatively affect public opinion. These included "ill-planned" transplant from non-human primates, discovery of new dangerous viruses, death of a patient from a pig virus infection, discrediting of an oversight authority to fulfill its tasks and creation of "widespread negative publicity" (ibid. 228). Daar concluded his presentation with lessons learned and set out a strategic map for gaining public acceptance, which included the role of the public ("publicity cuts both ways"), media ("can be fickle"), lobbying ("it works"), the importance of primacy, the imponderability of research, the uncertainty about infection risk, the easiness to find patients for clinical trials, the role of animal groups in shaping public attitude, the role of patients' advocacy groups (balancing the negative publicity of animal rights groups), and differences between the United States and Europe with regards to a moratorium (Europe being more in favor of a moratorium than the US). He also agreed to the necessity of some sort of "community consent" but said that "at present we have no sensible idea how to obtain such consent" (ibid. 230).

The strategic and instrumental approach to public involvement differs notably from the second and third approaches presented in the workshop, i.e. *involvement as helplessness and involvement as participation*.

3.3.4.2 Involvement as Helplessness

During the workshop, regulators and experts appealed regularly for the involvement of the public in a xenotransplantation debate. However, concrete suggestions of how to put this into practice and actual steps towards public involvement were almost nonexistent at the conference. This type of relationship with the public might be called *involvement as*

helplessness. This means that actors acknowledged the importance of public debate from time to time but this appeal remained mere rhetoric because no practical plans for how to accomplish this were mentioned.

Eric van Rongen, chairman of the Dutch Xenotransplantation Advisory Committee provided an example of this approach. He presented the Dutch Committee's recommendations, which stated that "it (the Committee) would consequently like to see information made available and the encouragement of public debate on these matters" (van Rongen 1998: 180). However, he did not delineate a process for how this might be realized.

Rashid Shaikh, from the New York Academy of Science, provided another example by stating that one should be sensitive about public perception and acceptance by including issues such as trust, religious and cultural values. "The public perception of risk is central to the acceptability and successful implementation of clinical xenotransplantation. (…) It is important to be sensitive of these issues in formulating national and international policy" (Shaikh et al. 1998: 203ff.). But he also did not provide an answer on how this goal might be accomplished.

At a press conference Jay Fishman brought this helplessness to the point by stating that "the question was: how do we best involve the public in discussions of a risk that potentially involves the public at large? It is clear that we don't know the answer to that." (Jay Fishman in Shaikh et al. 1998: 247).

As will be shown later in this paper, the *involvement as helplessness* together with *involvement as public relations* approach was also dominant within the OECD.

3.3.4.3 Involvement as Participation

André LaPrairie and D. Brodie (1998), two policymakers from Health Canada, addressed the problem of loss of public confidence in government regulation, which was caused by increasing threats – they provided HIV and mad cow disease as examples - and previous regulatory failings. Regulators would also face society's additional demand to "look beyond safety and risk management and address overriding issues of ethics and economics" (ibid. 171). They therefore concluded that public demand on regulation had increased and it had become increasingly difficult to satisfy. Their approach to regulation, which might be called *involvement as participation*, therefore emphasized "not only decisional efficiency, but also transparency, participation, and accountability" (ibid. 172). Participation would lead to transparency, and consequently would contribute to trust in regulatory bodies and regulations. They therefore argued for open decision-making processes involving the public:

"Negative impressions of government have been linked to a poor understanding of how government decisions are actually made. Openness in regulatory decision-making means

that stakeholders – including the public – are given reasonable notice, reasonable opportunity to observe the decision-making process and reasonable access to relevant government documents and information. Participation in regulatory processes, while not as accepted a practice, may also lead to better perception of transparency" (ibid. 172).

Another problem they addressed in their presentation were the differences between experts' and the public's risk perception. They argued: "the information provided by experts or regulators may be accurate, but if it does not address public perceptions or fears it will only compound the issue and increase public anxiety. This risk information vacuum can also amplify perceived risk and decrease trust in the regulator" (ibid. 172).

This was also a challenge for xenotransplantation, which would raise "psychological, cultural and societal concerns that require frank public debate and the dissemination of accurate information" (ibid. 173). They therefore argued for a regulatory strategy emphasizing openness to the public and building of trust:

"Public communication and consultation are fundamental elements in the development of any regulatory framework. The benefits of public confidence must be understood by the regulator so that resources appropriate to this objective can be obtained. How the regulator manages and communicates the scientific, social, cultural, legal, and ethical issues of biotechnology such as xenotransplantation will influence public trust in both the technology and the regulator" (ibid. 175).

This approach, which is open for framing by the public, is consistent with the participatory approach taken by Health Canada in discussing Canadian xenotransplantation policies (Einsiedel et al. 2011).

Another example for appeals to involve the public is Jay Fishman. In his introductory article he claimed that there is a central role for authorities to exchange information but "the public must be informed and involved in the developmental process for regulatory guidelines" (Fishman et al. 1998: xii). In a press conference he reported that his initial motive to support a moratorium was to involve the public in discussing the potential risk of xenotransplantation for society. The installation of oversight of xenotransplantation satisfied this need in his opinion (Shaikh et al. 1998: 239, 247).

3.3.5 Output

The OECD New York Workshop resulted in two kinds of output. The first was a special issue of the Annals of the New York Academy of Science published in the same year (Annals New York Academy of Sciences 1998). This scientific publication provides all presentations with the exception of the concluding session. The second output was the official document

"Xenotransplantation. International Policy Issues", which was published one year later (OECD 1999). The following section deals with this publication.

3.4 Xenotransplantation - International Policy Issues

The 1999 OECD report was written by Elletra Ronchi, who already prepared the 1996 background paper and was the person within the Secretariat who played the largest part in organizing the New York Workshop.

The report is based on the presentations, transcripts of round table discussions and comments raised at the New York Workshop and is complemented by more recent scientific reports and regulatory developments. Drawing on Elletra Ronchi's background paper from 1996, it additionally provides an overview on policy issues in xenotransplantation and on international xenotransplantation policies.

However, the report differs from the 1996 background paper in one important way. As stated in its foreword, the document was edited and commented on by speakers, panel discussion members and rapporteurs. In contrast to the 1996 single-authored background paper, it has been read and accepted by competent researchers in the field of xenotransplantation and related areas and policymakers who participated in the New York Workshop. Moreover, it was submitted to the WPB'S Working Group on Human-health-related Biotechnologies and was discussed at one of its meetings (OECD 1999: 3). It became an official publication of the Secretary-General of the OECD. Thus, acceptance by experts, policymakers and OECD bodies strengthened the paper's legitimacy and social robustness as a policy document (see 2.1.4, 5.1.4).

3.4.1 Content

In this paper xenotransplantation is again framed in the context of transplantation research, which is presented as successful, widely accepted and, as a result facing, the problem of organ shortage. The report discusses organ procurement as a means of improving donation rates, providing Spain as an example for a successful organization of transplantation. Similar to the 1996 background paper, it discusses immunological hurdles of transplantation and methods to overcome rejection. Turning to xenotransplantation, the report provides a history of its development, and discusses pigs and baboons as donors and the respective physiological problems and infection risks. The report enters into international policy issues with xenotransplantation, providing information about international surveillance (notification, registry systems, archive system), international cooperation and developments of national and international draft guidelines on xenotransplantation in the Netherlands, Sweden, Spain, Switzerland, France, Germany, the US, Canada, the UK, the WHO and the Council of Europe. After mentioning lessons learned in gene-therapy, enterprises involved in xenotransplantation research are listed and economic aspects of this therapeutic approach

are discussed. The report refers to legal and ethical aspects, addressing legal issues, animal welfare and husbandry, public perception and developing countries. The report ends with some concluding considerations. The following section will focus on the perception of the public as well as on general conclusions.

3.4.1.1 Public Perception

The report recognizes a "fundamental need to stir social debate on the complex issues raised by xenotransplantation" (OECD: 1999: 69) and "international discussion" (ibid.). Taking up the formulation of Sergio Bellucci et al (1998), a group of Swiss and German researchers who carried out a qualitative survey on attitudes towards xenotransplantation, it reports that xenotransplantation in public discussion "is still considered more of a promise than a remedy" and as uncertain as its alternatives (ibid.). Resonating LaPrarie and Brodie's (1998) workshop contribution, it states that, "public confidence in the process of policy development is an essential element of a regulatory framework". It argues against a moratorium, again following LaPrarie's and Brodie's argumentation, that "such legislation tends to cut off public debate and create a (false?) (sic!) sense of resolution whereas in fact, the technique may well be developed elsewhere". The OECD approach is instead to "strictly enforce guidelines, with as much international consensus as possible, together with an ongoing ethical, scientific and public review of what is ethically permissible and scientifically possible and safe way constitute more effective means of oversight" (ibid. 70). OECD 1999 quotes directly from Jay Fishman (1998), when it states that "ethical principles are generally universal, but need interpretation in the light of local cultures, religions, economics, and laws. Legal protection must be established to provide human dignity and autonomy and to avoid the perception of exploitation in the developing world by the sponsors of novel technologies" (Fishman et al. 1998: xi).

How does this report conceive of a public debate? Public debate "should be informative and transparent, since low public confidence may be the result of a lack of information. The information put forward by experts and regulators may be accurate but if it does not address public perceptions or fears, public anxieties are very likely to increase. Thus, the use of terminology and language is very important and public debate should address psychology as much as science" (ibid. 70). How things are presented will be important: "one can anticipate high acceptance rates if the benefit to mankind is clear, ambivalence if the outcome is uncertain and strong disapproval if the process is perceived primarily as a source of commercial profit" (ibid. 71). However, no suggestions are made in the document about the format of such public debate. The public is perceived as an outsider who has to be won over by appropriate strategies, communication wording and techniques. The OECD therefore, in the same way as several of the experts' presentations at the New York Workshop, perceives of public involvement as a mixture of *helplessness* and *public relations*.

3.4.1.2 Ethical issues

The document lists a number of ethical concerns that need to be addressed:

- “may not be consistent with striving for humane and fair medicine;
- may conflict with efforts to develop better approaches to preventive medicine;
- may conflict with efforts to keep medical costs down;
- may contribute to the development of multi-tier medicine;
- may discourage donation of organs for allotransplantation” (ibid. 71).

However, although these problems are listed, they are not discussed in depth, neither at the conference, nor in the report.

3.4.1.3 Conclusions

The OECD report concludes that

- The economic impact of xenotransplantation is so far not adequately addressed in international discussion.
- Alternatives to xenotransplantation should be further pursued, including prevention and alternative approaches such as artificial organs and tissue engineering. Moreover, measures to increase organ procurement should be continued. However this will not be sufficient to alleviate organ shortage.
- Xenotransplantation necessitates the establishment of a global and wide-ranging surveillance regime, which includes risk assessment, risk prevention (by appropriate animal husbandry and lifelong patient monitoring), risk management, archives, guidelines, international standards, notification system, and registries. The OECD and other international organizations can play a role in that. Industry has to be involved in these efforts.
- Animal welfare should be at the highest possible standards and there is need for international harmonization in that.

- In general xenotransplantation might become a reality; a global surveillance regiment will be necessary; the public has to trust science and regulators and proper communication is necessary to ensure that.

In summary, a civil servant remembered the workshop as important to promoting an international dialogue and to setting the stage for policy making:

"it created international momentum, it created a base for international dialogue and it did point towards a few of the real major issues that needed to be addressed but it also cautioned that it was not going to resolve at that point, the shortage of donors. It gave everybody a sense that perhaps progress was going to be slower than one would think. There were many questions that were to be resolved and so policy-makers did not have to feel that they were under pressure and the biggest issue as I said that was then started to be discussed here was how then to act at policy level. Should we let it happen? How should we let it happen? How should the international community then go about it? Should we have some code of conduct in place? How to put in place the appropriate surveillance? Should there be a moratorium or not? Should we stop and wait? Is that feasible? So in some ways it created the right environment to ask all of these questions but it could not answer them all" (iv: 319-330).

3.5 Paris Workshop

3.5.1 Framework Agreement between OECD and WHO

On 30.11.1999 the OECD published a framework for co-operation between the OECD and the WHO, which among other topics lists cooperation "to develop guidance on surveillance and biosafety in relation to organ transplantation biotechnology, in particular xenotransplantation". These should build on various WHO activities in this area as well as on the OECD New York Workshop. During 1999-2001 the organizations will aim "at developing a shared system for monitoring advances in regulatory frameworks in these areas" (OECD 1999: 3).

3.5.2 Objective

The OECD/WHO Consultation on Xenotransplantation Surveillance took place from 4-6 October 2000 at the OECD Headquarter in Paris. The Consultation was jointly sponsored by the OECD, WHO and Health Canada.

The goal of the Consultation was to assemble "epidemiologists, infectious disease specialists, clinicians, industry, government and international organization representatives and others working in public health and xenotransplantation research to discuss and exchange ideas on the desirability of and possible approaches to xenotransplantation and

associated infectious disease surveillance, both at country level and internationally" (OECD/WHO 2001: 4). The purpose was therefore a further step downstream towards the realization of xenotransplantation. It was no longer a question whether clinical trials in xenotransplantation should be carried out but how they should be regulated nationally and internationally in terms of risk prevention and surveillance.

The questions posed in the consultation where therefore: (1) how can a xenogenic infectious disease event be defined? (2) Which lessons from existing surveillance systems can be drawn for xenotransplantation? (3) How can existing surveillance systems be adapted to the specifics of xenotransplantation? (4) Which ethical considerations have to be considered in surveillance systems? (5) What might a practical framework for international surveillance look like? (c.f. ibid.).

3.5.3 Participants

Table 4 Participants by Country

Country	**Number of participants**
France	8
UK	8
USA	7
NL	4
CH	3
CAN	3
Germany	3
WHO	3
European Commission	2
Italy	2
OECD	2
Spain	2
Sweden	1
AUT	1
AUS	1
Belgium	1
Denmark	1
Japan	1
Oman	1
Thailand	1
UNDP	1
	56

(Source: OECD/WHO 2001)

Table 9 shows that with approximately 50 participants the Paris Consultation was much smaller than the New York Workshop. Again the US and the UK were the countries with the most participants. However, given that the meeting was in Paris, there were many participants from organizations located in France, which accounts for the relatively high number of participants labeled as “French”. Again, Member State representatives as well as representatives of UN organizations and the European Commission were present.

Regulators were the largest group, followed by researchers in academia, hospitals and national research institutes and industry (see Table 10).

Table 5 Participants per type of organisation

Type of organization	**Number of participants**
National and international regulatory authority	26
Research at hospitals, universities, national research institutes; research funding	16
Industry	8
International Organizations	6
	56

(Source: OECD/WHO 2001)

3.5.4 Output

As described in a “note by the secretariat” the report was again prepared by Elettra Ronchi with “contribution and input” from a WHO official and notes from the rapporteur of the consultation. Again, the report was distributed for comment to participants and revised thereafter. The revised report was submitted to the Working Group on Human Health-Related Biotechnologies and the WPB and became declassified by the Committee for Scientific and Technological Policy (CSTP) on 19. October 2001 (OECD/WHO 2001: 2). Thus it is a final and official document of the OECD. Moreover, being a joint document of two international organizations, its social robustness was again amplified.

OECD/WHO policy can be summarized in general as being positive towards xenotransplantation, however, with an emphasis on strict surveillance and international cooperation. Since “significant scientific advances are rapidly paving the way to xenotransplantation” and because “of the potential risk of xenogenic pathogens”, the report states that “international surveillance for xenotransplantation-associated infectious disease is needed” (ibid. 4). The objective of such surveillance would be to “detect and report xenotransplantation-derived infectious disease events” (…) share information and cooperation; facilitate xenogeneic disease events verification and response co-ordination” (ibid. 5). Countries that want to carry out clinical trials agree to “designate resources to establish a national xenotransplantation surveillance system” and a “xenotransplantation

registry" and "facilitate international exchange of information, which protects the confidentiality of individual patients and investigators" (ibid.). Information sharing and cooperation should build upon existing infrastructures and the WHO, OECD and Council of Europe should take leadership roles in that.

Most of the document is rather technical and goes into details about finding a consensual definition of xenotransplantation and adapting existing systems of informing, monitoring, controlling, breeding and reaching standards necessary for safe xenotransplantation to be carried out. Although it would be interesting to analyze in detail how the public is positioned by the proposed surveillance system, the following section will limit its scope to the way in which the document explicitly talks about the public.

The section "ethical considerations in xenotransplantation surveillance" starts out with the notion that experiences with applications of biotechnology proved that debate with the public on social and ethical issues would be crucial for acceptance (ibid. 20). This would also be the case for xenotransplantation, which would need addressing of a "broad range of ethical implications, including the feasibility of xenotransplantation and of the surveillance schemes" (ibid.). The report lists five unresolved questions of xenotransplantation surveillance, which would need consideration: "(1) protection of patients' privacy and confidentiality. (2) Conflicts between private vs. public interests. (3) The potential for infringement of human rights of first recipients. (4) Intersection between domestic and international law. (5) Appropriate action in the case of xenogeneic infection" (ibid. 20).

The document also briefly raises the question of "how can the public be engaged in a meaningful way?" (ibid.). But it does not address this question in any way; instead it immediately goes on to discuss the ethical problems of xenotransplantation clinical trials for individuals (ibid. 21). Thus, again, *public involvement* is dealt with as *helplessness*.

With the Paris Workshop, the OECD's involvement slowly fades. In the aftermath of the conference, Health Canada and the WHO organized an Electronic Discussion Group (WHO 1999). Elettra Ronchi participated as moderator, but the OECD did not the organizing. Furthermore, the OECD compiled a data base of regulatory developments in xenotransplantation in OECD Member States, which has not been updated since 2001.[10]

3.6 Summary of OECD xenotransplantation policies

In summary, OECD xenotransplantation policies have several main characteristics:

OECD activities were triggered by Member States and contributed to putting xenotransplantation on an international agenda. The OECD achieved this by providing a

[10] http://www.oecd.org/countrylist/0,2578,en_2649_34537_1783767_1_1_1_1,00.html, download: 14.08.09.

policy forum of mutual exchange with its workshops and reports. This, according to an interviewed civil servant, "stimulated a great deal of international discussion, which of itself (…) was very helpful" (x: 88-90).

The OECD framed xenotransplantation in the context of science, the interests of transplantation patients, public health and economics. It discussed xenotransplantation from a perspective on organ shortage, risk prevention and surveillance, its benefits for people waiting for transplantation as well as the economic impact of xenotransplantation.

Instead of a moratorium, the OECD favored harmonized international surveillance. It contributed to the formulation of elements of such a global surveillance system.

The OECD perceived a moratorium as a controversial issue because the Council of Europe was discussing it at that time. According to a civil servant, the OECD did not consider a moratorium as a “good tool" in a "global" and "international environment" because "somewhere it's going to happen" (iv: 165-175). The attitude taken was therefore: "we know that eventually there could be a risk of something happening, so let's see what we need to put in place in order to avoid (...) the hazard" (iv: 175-177). Thus, "the so called OECD approach which meant ‘No we are not going moratorium we are going for close, very close regulation, very careful regulation’" (iv: 444-445). One reason for that was the concern that a moratorium would export the problem to less developed countries where it was outside surveillance: “We just didn´t think that that was going to work because the science and the trials were still going to go ahead and the worse of it all they might have even been exported outside of the OECD countries where the regulatory frameworks were in place" (iv: 458-460).

Finally, the OECD moved the agenda to the WHO.

A OECD civil servant recalled that the WHO had problems in getting a political mandate to look into xenotransplantation. The OECD had an important role in putting xenotransplantation on the agenda of this other international organization: it "pushed the recommendation at the executive board of the WHO" (iv: 239-244). Because of its lack of legal competence, the OECD thought that it had done its job by organizing the New York Workshop and the OECD/WHO Consultation; “there were recommendations and the recommendations were directed at other organizations that was appropriate, other organizations, either international organizations, sister organizations or in fact national governments and it was for others to pick up those recommendations. (…) There is no mandate for the OECD to instruct other organization to work in these areas” (x: 113-127). After the OECD/WHO Consultation the topic moved to the WHO and the international online consultation (iv: 370-379). When it came to the details of the surveillance system "it was clear that much of this really needed WHO action at this point" (iv: 431-432).

4 Actors

The following section shortly describes the actors engaged in the aforementioned policy process.

4.1 National Governments

National governments played an important role in whether and in what way xenotransplantation was dealt with in the OECD. National governments of the US, UK and Canada were putting xenotransplantation on the agenda via their delegates in the WPB. They were doing this because of their own needs; the UK and the US as countries hosting leading research, and Canada, because it struggled with appropriate xenotransplantation regulation. Together with the governments of Germany and Switzerland they co-financed the New York Workshop and thereby promoted an international exchange. They provided their experiences at the workshops and contributed to and decided upon international standards.

4.2 Committee and Working Groups

The WPB played a fundamental role by putting xenotransplantation on the OECD work programme, defining the issues to be addressed and funding this activity. The WPB conveyed legitimacy to OECD documents by declassifying and acknowledging them as official papers.

4.3 Secretariat

Although the Biotechnology Unit, with only three employees, is anything but a big unit, the OECD Secretariat was central for the development of OECD xenotransplantation policies. A single civil servant, Mrs. Elettra Ronchi, did the main share of the detailed work of pulling together scientific information, drafting and rewriting reports, planning and organizing workshops, keeping records and editing documents. Different from the WPB members, who assembled twice a year, this civil servant continuously dealt with the tasks for a long period of time. In doing that, she expanded her network of key actors in research, industry, national governments and international organisations.

4.4 Researchers

Researchers were a very strong group within the OECD network. First, many national delegates were trained as researchers (civil servants were often also scientists, and national governments also nominated researchers as delegates). Second, the responsible civil servant in the OECD, as already said, was a trained scientist. Third, naturally researchers were “the” core experts, the insiders in xenotransplantation. They knew about

transplantation, physiology, immunology, infection risk, cloning, genetics, veterinary medicine, etc. Thus, researchers were already involved as members of the WPB and more experts were invited as additional key informants. Experts played a fundamental role in developing OECD policy. As an interview partner recalled: "the experts were involved absolutely critically in the early stages of defining the issues, to examine further and these were experts at a national level, but very quickly plugged into the OECD machinery. They were involved throughout in drafting information, in presenting and helping to facilitate the meeting and in helping with the final reports when they were produced" (x: 98-102).

4.5 Industry

The OECD focused on xenotransplantation from an economic angle: What can biotechnology do for economies? What are the obstacles? Industry was therefore very strongly involved in policy making, e.g., in the preparation of the New York Workshop (see 3.3) and in attending the workshops (see 3.3.1, 3.5.3).

4.6 NGOs

In contrast to experts, policymakers and industry, only few NGOs were involved in OECD policy making. NGOs were not involved in the preparation of the New York Workshop and only three NGOs attended the conference, i.e. two patient organisations and one NGO, advocating animal welfare.

One of the NGOs present was the Islet Foundation, which attended the meeting with two people for “representing the interests of the diabetic community” (Islet Foundation n. d. 2). It perceived xenotransplantation potentially “as the only hope for a cure in the near future”. It argued against a moratorium because “any regulatory impediments to the advancement of xenotransplantation would have serious consequences for those seeking to end diabetes” (ibid.). Because several countries were thinking about a moratorium it “was essential that our voice be heard in an international forum were such regulatory arguments would be aired”. They reported that the workshops gave them the impression that “it was generally recognized that the benefits of xenotransplantation are enormous and the risks manageable” (ibid.). They wanted to speed up the process towards clinical trials. “Now it’s time for some action. By this time next year there should be some real progress, and we must not find ourselves still talking about the same things. This is all about clinical trials, not about endless process” (ibid. 2).

4.7 Public

As can be seen from the previous actors, the OECD used a close and closed international network from national and international policy making, research and industry. The public was

only included via press conferences and the possibility to read the reports, which were published on paper or the Internet.

5 Social Practices

The following section is dedicated to social practices within the OECD that have an impact on the potential of citizen involvement. It will analyze how topics are put on the OECD's agenda and how OECD activities are funded. It will continue by discussing the OECD's "idea game", the organization's impact on national policy making, the importance of consensus within the OECD and the process of declassification. This will be followed by a summary of the role the public is playing in the OECD's policy making.

5.1 Social Practices in the Field of Policy Making

5.1.1 Putting Topics on the Agenda

One organizational process that respondents frequently addressed in interviews was the constant differentiation of topics and a strong tendency to create new Working Parties. There is a dialectic relationship between extending the scope of topics according to necessity and limiting their number to a workable size. An interview partner criticized the OECD for engaging with too many topics and for the creation of new Working Parties each year despite their already great number (iii: 85-87). In principle, the Council would therefore want to limit their number; a counter argument to this policy of limiting growth was put forward by another interview partner, who argued that the OECD could not seriously consider itself to be a think tank if it would neglect important topics (vi: 74-82). Thus, there is a certain tension between these two approaches. For the scope of this paper it is important to notice that, as in any other organization, topics emerge, develop and sometimes disappear within the OECD. The central questions therefore are: how does the OECD arrive at new topics and who takes the initiative in that?

The subjects the OECD intends to deal with are laid down in a so-called "work program". This paper, which is renewed every two years, defines tasks and working areas. Together with the budget it is a key instrument for planning. What is on the work program and budgeted for will be dealt with. Any OECD actor who wants to have a particular topic on the agenda has to make sure that it is put in the work program. Topics are first discussed and negotiated at the Committee level and then aggregated in the work program (v: 206-212, 218-221). There are several ways to get an issue on the agenda.

Topics often develop from previous activities in Committees (vii: 143-151). As one OECD expert put it: "in practice it is often the case that things result from previous work and are a sort of continuation" (v: 227-232).

Sometimes Member States take initiative within a specialized Committee or Working Party and ask the Secretariat to deal with a topic (vii: 126-140, see 3.1). This is preceded by informal exchange between Member State representatives. Several interview partners emphasized the fact that the OECD is "Member State driven" (ix: 3); that means it is primarily Member States that define OECD activities (i: 88-94, ix: 39-40). They announce their requirements and needs in the Committees (v: 232-234). They are the ones who have the last word because "finally, the competence is with the Member States, finally Member States have to approve of the plans" (v: 235-236).

However, not only Committees but also the Council or the Executive Committee might put a topic on the research agenda because they might consider it as a basic decision and top priority (see 2.3.1). The topic “green growth”, which was recently intensely discussed in the OECD, is an example of this "top-down-approach" (vii: 73-89, 154-156).

Initiative to look into a policy area can come, and this is very often the case, from the Secretariat itself. One interview partner gave an example of how in the early 1990s a staff member initiated the OECD’s involvement in health policy from scratch within the already existent policy area of social policy because he considered it an important topic (interview i: 16-18, 39-43).

In practice topics are selected in cooperation and consensus between the Secretariat, the chair of a Working Party and a Committee. As a civil servant explains, "it can emanate from the committee, it can emanate from the Secretariat. Particularly in the Working Party on Biotechnology there are a number of very active countries, which are also represented in the board, and proposals for topics are literally coming from all sides" (ix: 144-147). The discussion and selection of future topics is not settled once and for all but it is a constant issue at each meeting (ix: 129-140). At times there might be tensions between different actors, whether an issue should be dealt with or not. A Committee, for instance, might consider a topic, the Secretariat proposed as less important and decline to look into it (vii: 143-151). In this situation, a rejected topic might reemerge through the backdoor because the Secretariat still wants to continue with an activity it has been engaged in for years (ii: 106-111 and Committee and Secretariat might even come into a "close fight" (ii: 110) over the work program. One interviewee called this process "persuasion between partners" (v: 234).

In summary, topics do not develop quasi naturally but have to be put on the agenda. There are certain reasons why different topics are on the agenda and others are not, i.e. there are certain interests involved in certain topics. Sometimes there are frictions between different OECD bodies and also between Member States about making an issue topical or not.

Xenotransplantation was not a core topic of the OECD but rather marginal to its interest. It was put on the agenda by several Member States who had an interest in looking into the

area and putting it on the international agenda because of research activities in their own countries and/or concern about the implications of risk and public health.

5.1.2 Funding

Appropriate funding is an important bottleneck for any actor who wants to put an activity on the OECD agenda. The OECD is funded by its Member States, in the form of basic - obligatory contributions based on the country's Gross Domestic Product - and additional funding, the so called voluntary contributions. Several interview partners explained that basic funding was often insufficient to carry out necessary work. The OECD would lack money and basic funding would cover only 50 to 75% of its costs (ix: 89). Money for analytical projects would often be short (i: 88-94). Obligatory funds cover "secretariat salaries, missions, paper, internal operations". However, in order to do additional activities "voluntary contributions (…) are necessary to fund workshops, to fund case studies" (iv: 212-219).

It therefore often needs additional funding by voluntary contributions from Member States to put a topic on the agenda and finance an activity. It is either a group of countries or, in rare cases, a single country that finances such additional activities (i: 104-107). It is one of the tasks of Committee Chairs and the Secretariat "to fill the work program with life" and to raise voluntary contributions (ix: 95-96).

Voluntary contributions, which increased "enormously" in recent years (iii: 30-32), were also critical in the case of xenotransplantation. They came, as previously mentioned, from a number of Member States, which were particularly interested in the topic (see 3.1). David Harper, the Chairman of WPB and the Working Party of Human Health Related Biotechnology, was a UK delegate from the Department of Health and was particularly interested in the topic. Several Member States co-financed the New York Workshop (see 3.3) and the Paris Consultation (see 3.5.2) and therefore made OECD engagement possible.

5.1.3 "Idea game"

The OECD does not distribute money (OECD 2008: 13). It "provides a setting for reflection and discussion, based on policy research and analysis, that helps governments shape policy that may lead to a formal agreement among member governments or be acted on in domestic or other international fora" (OECD 2008: 13). Because it neither distributes money, nor issues formal legislation to any significant extent, the OECD "is bound to play", as Marcussen put it, "the so called idea game" (Marcussen 2004: 15, see 1.1). So how does the OECD actually play this game?

5.1.3.1 Bringing Together Experts

One way of playing the idea game is to create and promote a network of actors active in xenotransplantation policies. Workshops, consultations and Internet discussions were means to this end.

At the time of the New York Workshop, the workshop format was already an established instrument within the OECD's human health related biotechnology policy. The New York Workshop was preceded by similar events on "Non Target-Effects of Live Vaccines" in 1992, "Gene Delivery Systems" in 1995 and "Novel Systems for the Study of Human Disease" in 1996 (OECD 1996: 3). As Michael Oborne, Deputy Director of the Directorate for Science, Technology and Industry at the OECD mentioned in his introductory comments at the New York Workshop: "the OECD community used the workshop as a means to facilitate exchange of experience, the development of common concepts and approaches. We hope that this workshop can achieve similar objectives and will lay the grounds for productive international co-operation and co-ordination" (Oborne 1998: xviii).

The New York Workshop was a place where people active in xenotransplantation research and policy making were deliberately brought together by the OECD to exchange their experiences. As can be seen from other CIT-PART case studies, actors who were relevant in their national xenotransplantation policy from Austria (Griessler/Biegelbauer 2012), Canada (Einsiedel et al. 2011), the Netherlands (Versteeg/Loeber 2011), Sweden (Hansson/Lundin 2011), Switzerland (Griessler 2011) and the UK (Brown/ Beynon-Jones 2011) as well as Council of Europe and WHO representatives participated in this meeting.

However, the New York Workshop and the OECD/WHO Consultation were not the only events where this international network met. Jay Fishman et al. (1998: ix) in their preface referred to "three years of intensive discussion on the part of regulatory authorities, transplant physicians, scientists, ethicists, and other experts sponsored by public health agencies of the United States, Great Britain and Canada, by the Institute of Medicine of the National Academy of Science, by the World Health Organization, and other organizations concerned with the issue". The OECD/WHO-Consultation builds directly on experiences gained in previous international settings such as a WHO Consultation, The Canadian Forum 1997 (Einsiedel et al. 2011), the OECD New York Workshop and the Meeting of UKXIRA in 1999. This indicates that the international dynamics of xenotransplantation regulation were based on an interweaving network of experts, industry representatives and national as well as international regulatory organizations.

5.1.3.2 Distributing Documents and Policies

In the context of labour market and welfare policy, Dostal points out (2004: 441) that studies from the EU and the OECD "provided each other with additional legitimacy and set the

agenda for (…) reforms" (2004: 441). UK committees such as the Nuffield Council for Bioethics (1996) and the Kennedy report (Advisory Group on the Ethics of Xenotransplantation 1997) were the first who worked out recommendations on the ethics and social acceptability of xenotransplantation. These first movers were very influential for defining the ethics of xenotransplantation because they set the stage for later national and international committees and were often quoted as authorities on the subject.[11] The OECD contributed to the dissemination of authoritative papers of early movers by publishing their summaries in its documents (OECD 1996, 1999).

More importantly, however, the OECD's own documents which were published in 1996, 1999 and 2000 as well as its website helped to distribute policy ideas on xenotransplantation.

5.1.4 Declassification

How does the OECD arrive at a report? As has been pointed out in this paper, there was a single civil servant within the Secretariat who drafted and wrote all the documents based on literature and minutes. The drafts were then submitted to experts and participants at the New York Workshop and the OECD/WHO Consultation who were invited to make informal comments. But there is also a formal discussion and clearance process. Every six months the Committees meet for a discussion of activities and documents. When the document is finally finished it is "declassified" by the Member States as an OECD document (vi: 55-59). Declassification "is neither problematic nor a formality, they (the Secretariat) often get a lot of feedback. In this sense it is important (...). (...) Sometimes it might happen that there are different opinions about a topic, which (the Committee) is made aware of. (...) In principle (...) it is a matter, which we perceive rather positively. We get a lot of feedback and a lot of things are brought to our attention we did not know" (v: 280-287).

As already mentioned, there is a degree of stratification within OECD bodies (see: 2.3.2). Working Parties are at an expert level, Committees operate at the level of civil servants and Council at the level of Ambassadors. If conflicts occur during declassification, an attempt is made to solve them at an expert level in the Working Party because at that level there is the most expertise. Civil servants and, to an even greater degree, ambassadors are less familiar with the topic. If settlement on Working Party level is impossible the issue moves to the Committee. If no solution is found at this level, which is an exceptional case, it moves up to the ambassador level. The process to declassify a document is called "declassification" (vi: 66-73).

[11] They can be used to legitimate one's own position, e.g. in the Dutch case: "The committee has taken note of the elaborate ethical considerations of the Nuffield Council of Bioethics and the Advisory Group on the Ethics of Xenotransplantation, both from the United Kingdom, and agrees with their conclusions" (van Rongen 1998: 179). The Dutch Committee came to the conclusion that "from a human point of view, xenotransplantation is ethically acceptable" (ibid. 180).

Declassification is not necessary in all OECD areas. In the case of xenotransplantation, the document went to the Working Party, to the Committee and "then a notice goes to Council. They don't have to say yes/no but it goes" there (iv: 383-388).

5.1.5 Consensus

Declassification means that the OECD has to approve of a document officially in a formal procedure. In this sense the OECD is a "consensus club" (iii: 46), a "consensus organization". The OECD is a "soft law think thank" (vii: 16) and makes consensual recommendations. Within the OECD there is an emphasis on trying to involve countries and on trying to get a consensus even when their policies are criticized. Thus, there is little voting in Committees, the development of guidelines and agreements is an "interactive" process between Member States (v: 12-13, ix: 156-160). According to a civil servant, critics might call this a "diluted" consensus.

5.1.6 Impact

In contrast to the European Union, which can directly issue regulations, directives and decisions, the OECD mostly works with soft law instruments such as best practices, recommendations, guidelines and agreements (v: 8-12, ix: 115-116). It is up to the Member States to decide how to make use of OECD results. No Member State is obliged or forced to accept recommendations. This soft law character provides the OECD with room for maneuver. It is a possibility for the OECD to bring together politics and science (vii: 23).

The OECD's impact derives from communication between experts and policymakers (policy forum), but also from peer review pressure among Member States (i. 100-102). As a civil servant described „there is a soft, it's not a tough, but a soft peer pressure" amongst civil servants in the OECD (v: 475-480). This is also recognized by the OECD, who states that "peer pressure can act as a powerful incentive to improve policy" (OECD 2008. 7). Peer pressure works particularly in the area of economic country surveys (Noaksson/Jacobsson 2003).

OECD results can be used by policymakers for policy learning, either by supporting their own position, but, and this might be less pleasant, also as a critique of their policy. OECD can help to bring domestic political debates on an objective level (iii: 453-471). As a respondent explained: "It is tremendously helpful if one is able to say: 'this is not only something the WIFO and the IHS (two Austrian research institutes) are saying, but that's something others are saying as well'" (iii: 544-546). One way to promote the impact of OECD analysis on domestic policy is inviting OECD staff to events in one's own country (v: 444-469).

Learning from the OECD however, is impeded by lack of time. The OECD Secretariat would be able to work continuously and for several years on one and the same topic. In contrast,

national civil servants because of their duties at their own countries and the EU would simply lack the time to go into a matter in such a detail; the impact of OECD documents would therefore vary to a great extent from topic to topic and country to country (iii 209-220).

5.2 Social Practices in the Field of Citizen Participation

There is no direct public participation in the OECD. The idea within the OECD is, that the public is represented by representative democracy. Committee members carry the political mandate of their elected governments and represent the public in that way (i: 144-145). The OECD's work is influenced by current political concerns via the organization's "political strand", i.e., the Secretary General and the OECD's political super structure of Council and Standing Committees.

An exception to this model is the involvement of traditional interests. The Trade Union Advisory Committee (TUAC) and the Business and Industry Advisory Committee (BIAC) have privileged access to the OECD (vii: 380-387). Both of them are allowed to participate in meetings as observers. They can ask questions but cannot file petitions. Moreover, they have to leave the room when decisions are made (ix: 279-296).

As a senior diplomat observed, in comparison to other international organizations, NGOs in the OECD are not a driving force and their integration is not very strong (ix: 31-34). The public plays a comparatively small role and apart from TUAC and BIAC there is little involvement (ix: 267).

The fact that there is little public involvement is best expressed by an interview partner who claimed that they did not perceive the OECD as "an open organization; instead, it's simply the case that civil servants sit inside (the OECD) and work with the problems they perceive, they identify" (vii: 346-348). Drawing from the interviews, public involvement apart from information is simply not part of the organization's self perception, which seems to be dominated by a deficit model according to which which lay people would lack sufficient knowledge to be involved. To inform the public would be a difficult task, which would not necessarily benefit the policy outcome.

According to one interviewee, the "OECD standard procedures provide for anything else than by the broader public, that's not the concept and idea, but the idea is, the OECD is an expert organization which answers questions posed to it" (ii: 24-27). According to another informant, the public is not involved and would be overburdened by the topics discussed. OECD documents would be very technical and only declassified documents are open to the public (vi: 95-99). This technocratic view is also shared by a respondent who said that, "the topics are highly complex (...) and the investment in time and resources necessary to involve a broad public would exceed the potential benefit" (ix: 300-302). This lack of public involvement is not perceived as a problem in the OECD's self-conception. The issues

discussed would be "very, very technical" and "the involvement of a broader public would probably not really be a benefit to the discussion" (ix: 274-275) because there would be great need for explanation. The policy process is perceived as driven by sound science and not by political negotiations. As an interview partner recalled the discussion on xenotransplantation: "this was (…) an expert driven process that was the (…) heart of the work that the Working Party did. So it was as far as evidence based approach it could be" (x: 233-235).

However, some informants stated that the OECD would have a public relation problem and would increasingly try in recent years to reach the public. This discussion seems to be more about selling the OECD to the public and how the public might use the OECD's output in terms of reports and data bases (vii: 94-104) than about public participation (vii: 87-90).

In summary, OECD documents provided different approaches to public involvement. Member State delegates at the New York Workshop presented approaches to citizen involvement such as *involvement as public relations, involvement as helplessness and involvement as participation*. Health Canada, e.g., presented a participatory approach which remained in stark contrast to the one the OECD used in its own policy development process and declared in its documents, in which public involvement was perceived as a mixture of *helplessness* and *public relations*.

6 Conclusions

The OECD's xenotransplantation policies - which included implicit technology assessment - developed through sequential interaction between the OECD Biotechnology Unit, the CSTP, its Working Parties, policymakers in international organisations and external experts.

The process started with the WPB's putting xenotransplantation on its work programme. This initiative was Member State driven and originated from the US, the UK and Canada. The WPB asked the Secretariat's Biotechnology Unit for a background paper to prepare a workshop, a format, which had already been applied twice for policy development within the WPB. The background paper was based on international literature and national statistics from the UK, the US and France and was subsequently discussed with, and authorized by the WPB. After passing a procedural shortcut, it was published as an official OECD document without having gone through the regular lengthy declassification process.

In order to organize the New York Workshop, the WPB installed an Informal Expert Group. The aim of the Workshop was to invite policymakers and experts to learn more about the science of xenotransplantation and necessary regulation. This Informal Expert Group laid down the workshop format, defined questions to be addressed and suggested speakers. The Member States were invited to nominate delegates. The conference included plenary sessions, formal presentations, questions and answers, and several rapporteurs.

At the New York Workshop experts from policy making and research (public and industry) addressed the questions posed by the Informal Expert Group in presentations. The papers were published in the Annals of the New York Academy of Science. The Workshop also resulted in an official OECD policy document. The expert in the Biotechnology Unit, who was responsible for the topic xenotransplantation, wrote another policy document which combined her former background paper with insights from presentations and conclusions from the Workshop. This document was presented to speakers for comments, revised and finally presented to the WPB for declassification. After a formal declassification process, it became an official OECD document.

The process did not stop at this point. The OECD organized a follow up event, this time in cooperation with the WHO, in order to develop guidance for international surveillance. The event took the form of a consultation. Again, the OECD/WHO Consultation was first planned and staged by a small group of experts and policymakers. Questions addressed in this preparatory stage were, e.g.: what is the purpose of the conference? Who is going to be invited? Who is going to chair what session? Who is going to be rapporteur? The Consultation followed the format of formal presentation and round table discussions. A rapporteur kept record of discussions and summarized them in a document, which was again

distributed to participants for comments. The latter were included in the draft paper and the revised paper was finally declassified by the CSTP. After being cleared, the documents again became an official document. However, this time it was authorized by two international organizations, the OECD and the WHO.

This process of policy development and implicit technology assessment took place, as just outlined, at many places within the OECD: the Biotechnology Unit, the Informal Expert Group, the Working Party on Human Health Related Biotechnology, the WPB, the CSTP, as well as at the New York Workshop and the OECD/WHO Consultation. It was driven by an international regulatory network, which included policymakers from Member States, international organizations and researchers from academia and private industry. The Biotechnology Unit orchestrated the OECD contribution to this international regulatory process.

The OECD framed xenotransplantation not as “whether” but as “when and how” it would happen. It mainly framed xenotransplantation in the context of organ shortage, sound science and economics. In the course of the two subsequent workshops in 1998 and 2000 the questions dealt with became increasingly downstream oriented and practical in the sense of how to put xenotransplantation safely into clinical practice. The OECD was not in favor of a moratorium because it considered it ineffective. Its policy approach was safe implantation and, as a necessary prerequisite, international surveillance. Ethical issues were listed in OECD documents but never discussed in any greater detail.

The OECD does not possess strong generalized symbolic media to advance its policies. In contrast to economic surveys, peer pressure is not very strong in the area of biotechnology in the OECD. It is therefore even more bound to playing the idea game to promote its policies. Together with the Council of Europe and the WHO, the OECD played an important role in putting xenotransplantation on the international agenda. It assembled key actors, provided an international platform, published documents, co-operated with the WHO to initiate international standards for surveillance and clinical practices, and finally moved the topic to the WHO.

The Biotechnology Unit is a very small unit in DSTI, which again is not the most prestigious OECD Directorate (see 2.2). Routine practices employed in policy making were: putting a topic on the agenda, writing official documents by a (single) staff member based on her own research, organizing workshops and consultations, arbitrating with the WHO and Member State representatives, and discussing and declassifying documents in an organization that has been described as a consensus club that can only issue soft regulation. Artifacts produced in this process include official documents (declassified reports, participant lists, and agendas) as well as unofficial documents (draft agendas).

The aim of the technology assessment was to exchange information, to acquire knowledge about the current state of the art research, to inform policy makers and experts about xenotransplantation and to recommend options for policy making on xenotransplantation. The Outcome of this processes were policy papers and recommendations.

Experts and policymakers in the OECD debated the topic of xenotransplantation. There was little NGO involvement, no citizen participation and no PTA. Citizens were only involved as consumers of official reports and information provided via the internet. The public, as perceived in OECD documents, was an opaque and silent majority, which OECD actors were unsure, and lacked knowledge about. They were perceived as media consumers and potential patients.

Gender related questions were not addressed in the process of policy development.

Public participation played almost no role in OECD xenotransplantation policies. In the context of citizen participation, the OECD can be characterized as impermeable for several reasons.

- The OECD is an etatist and political organisation, which, to advance its policies, engenders political mechanisms of powering within and between Member States. Member states not only have to define a political position in their home countries - which already often involves conflicts that require resolution - there are also political conflicts between OECD Member States caused by their different interests and positions. Examples of such tensions that needed political resolution mentioned in interviews, concerned research on international pricing of pharmaceuticals and the regulation of human genetic testing. Citizen participation would add to the complexity of this already highly demanding and complicated political process. Within the OECD settlement of such conflicts is mainly accomplished through an emphasis on consensus (declassification), arbitration, soft law and peer pressure.

- The OECD is a think tank and an expert organisation: it deals with topics that are often highly complex and technical with a perspective of sound science. The easiest way to get information about such issues is to ask other experts. In addition, Committee members and Secretariat staff are also often trained as scientists or economists. They are part of an international expert network.

- The OECD is an elite organization, the access to which is highly selective. Committee members are either government representatives themselves or experts, nominated by their governments. Participants at conferences are also Member State nominees.

- The OECD reproduces its own epistemic community; as an elite, expert and political organization, the OECD reproduces a fairly closed and homogenous international network of policymakers, experts and industry representative (BIAC). Access for non-experts and non-policymakers is extremely difficult.

- The expert and policymaker network decides whether issues become topical and in what way they are framed. Issues, in order to be discussed, have to become topical in the aforementioned close network, which is remote from the public and NGOs. Moreover, in order to deal with an issue, additional funding is often necessary, which again has to be provided by Member States.

- Because of the basic economic mission of the OECD, the closed expert and policymaker network, and the difficulties of finding consensus in politics on ethical issues, xenotransplantation is framed rather narrowly in the context of economics and sound science. Although ethical and upstream questions are raised in policy documents, they are rarely discussed. Issues discussed are focused on how to put xenotransplantation into safe practice. This pragmatic and seemingly apolitical approach is in itself highly political, making it difficult to address upstream questions.

- Within the OECD the deficit model is still dominant, which mainly considers the public as ignorant. In this model the public is excluded from policy making. Though the question of how to involve citizens is often asked in OECD documents, practical solutions to actually doing it are rarely given. Though the importance of the public for the acceptance of technologies is recognized, it is still perceived as an outsider, whose trust and acceptance has to be achieved. The OECD approach to citizen involvement is therefore a mixture of helplessness and public relations. NGOs - apart TUAC and BIAC – are little involved. Even national parliaments are considered as outsiders from the OECD's perspective. The public is not perceived as an actor who might contribute important ideas or knowledge to the policy process. It is considered as being represented by indirect political representation of Member State governments. Citizens are only informed through press conferences, the Internet and publications. Within the OECD, there is no dialogue with but a discussion about the public.

7 Annexes

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viii. Council member, 25.10.2010, Paris.

ix. Committee member, 26.11.2010, Vienna.

x. Committee member, 12.4.2011, telephone Interview.

7.3 Abbreviations

CIT-PART	Impact of Citizen Participation on Decision Making in a Knowledge Intensive Policy Field
CSTP	Committee for Scientific and Technological Policy
DSTI	Directorate for Science, Technology and Industry
EG	Erich Griessler
n.d.	No date

NYAS	New York Academy of Sciences
OECD	Organisations for Economic Co-operation and Development
PTA	Participatory Technology Assessment
TA	Technology Assessment
WPB	Working Party on Biotechnology
XTP	xenotransplantation
UNDP	United Nations Development Programme

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